PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2211589/EJ	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. PCT/AU99/00993	International filing date *(day/month/year)* 10 November 1999	Priority Date *(day/month/year)* 11 November 1998
International Patent Classification (IPC) or national classification and IPC **Int. Cl.** [7] C12N 15/00; A61K 39/12		
Applicant NORTH WESTERN HEALTH CARE NETWORK et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☒	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☒	Certain observations on the international application

Date of submission of the demand 5 June 2000	Date of completion of the report 27 September 2000
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer MADHU K. JOGIA Telephone No. (02) 6283 2512

NTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
[redacted]/AU99/00993

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

[X] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	YES
	Claims 1-17	NO
Inventive step (IS)	Claims	YES
	Claims 1-17	NO
Industrial applicability (IA)	Claims 1-17	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The notations of the citations (D1-D13) appear in the same order as that listed in the International Search Report.

Novelty (N) and Inventive Step (IS) Claims 1-17

The present invention relates to an isolated Hepatitis B Virus (HBV) with a surface component (antigen) exhibiting an altered immunological profile relative to a reference HBV. Further, generic antigens include amino acid sequences as illustrated by formulae I, II and III.

However, the surface antigens are specifically disclosed and taught in the prior art, including D1 (J Virol; 1993) and Accession no JQ 2075 from PIR (compared to formula I); D2 (J Med Virology;1995) and Accession No BAA 04075 from GenPept (compared to formula II); D3 (Virology;1990), D4 (J Gen Virology; 1988); D5 (Vaccine;1998); D6 (J Gen Virology; 1985) and Accession No M 23808 from Genbank (compared to formula III).

Further patent documents D9, D10, D12 and D13 generally disclose and teach HBV surface antigens as defined in your application.

Moreover, it is not clear from the results of your invention whether the mutations as defined in claims 10, 11 and 12 demonstrate an advantage over mutations disclosed in the prior art. In the absence of any distinct advantage over the art, claims 10, 11 and 12 are not novel.

Therefore the invention as defined in claims 1-17 is not novel and lacks an inventive step.

The P,X document (D11) is not discussed in this section. However, details of the document are available in Box V1, Certain Documents Cited.

Industrial Applicability (IA) claims 1-17

The invention appears to possess industrial applicability.

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
WO	19/08/99	10/02/99	11/02/98

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1 and 2 are not fully supported by the description. Claim 1 defines any variant HBV comprising a surface antigen exhibiting an altered immunological profile compared to the reference HBV. However, the applicant has identified specific mutations compared to the known reference HBV of formalae I, II and III and which appear to be supported by Table 2. It would require or impose an undue burden of experimentation on the part of the skilled addressee to determine which antigens fall within the scope of the invention.

This objection also applies to claims 13-17.